

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PLASTIC SURGERY ASSOCIATES, S.C.,
a Wisconsin corporation, INFINITY SPA
ORLANDO, LLC, a Florida corporation,
GREEN CHRYSALIS ENTERPRISE, LLC
d/b/a THE FACE PLACE, a Texas
corporation, RENEW SKIN & LASER
CENTERS, LLC d/b/a DERMACARE OF
HAMPTON ROADS, a Virginia corporation,
ARIZONA ADVANCED AESTHETICS,
PLLC d/b/a ENHANCED IMAGE MED
SPA, an Arizona corporation, ADVANCED
HEALTH WEIGHT LOSS, S.C. d/b/a
OPTIONS MEDICAL WEIGHT LOSS, an
Illinois corporation, *on behalf of themselves
and all others similarly situated,*

Plaintiffs,

v.

CYNOSURE, INC., a Delaware corporation,

Defendant.

Case No.

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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Plaintiffs Plastic Surgery Associates, S.C., Renew Skin & Laser Centers, LLC d/b/a Dermacare of Hampton Roads, Infinity Spa Orlando, LLC, Green Chrysalis Enterprise, LLC d/b/a The Face Place, Arizona Advanced Aesthetics, PLLC d/b/a Enhanced Image Med Spa, and Advanced Medical Weight Loss, S.C. d/b/a Options Medical Weight Loss bring this Class Action Complaint against Defendant, Cynosure, Inc. Plaintiffs bring their claims on behalf of themselves and all others similarly situated for the false and misleading representations and omissions of material fact made by Cynosure to them regarding the SculpSure Non-Invasive Body Contouring Platform. Plaintiffs allege the following based upon personal knowledge and experience, and as to all other matters upon information and belief, including investigation conducted by its attorneys:

I. NATURE OF THE CASE

1. In 2015, Cynosure, Inc. began selling the SculpSure Non-Invasive Body Contouring Platform (“SculpSure”) to physicians, aesthetic surgery practices, and medical spas (or “med spas”) across the United States. Cynosure marketed SculpSure as an effective way for the medical practices to reduce fat in a patient’s midsection through the use of laser technology.

2. As part of an aggressive campaign to induce Plaintiffs and the Class to purchase the almost \$200,000 machine, Cynosure made several uniform material misrepresentations regarding the key attributes of the SculpSure device. Cynosure uniformly claimed that: (a) only one, simple 25-minute treatment achieved 24% fat loss; (b) SculpSure is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) the procedure could be performed “hands free” without a physician or trained staff member needing to be present during the majority of the treatment.

3. Yet Cynosure's representations have proven false. SculpSure seldom achieves results in patients after *multiple* treatments—much less so with just the single procedure Cynosure claimed would suffice. And to even have a chance at achieving results, operators must turn the power level so high that it causes intolerable pain for the patient, necessitating that the operator remain in the room to monitor patient comfort. In some cases, the operator must stop the procedure altogether.

4. Practices across the country have thus found SculpSure detrimental to their business.

5. By recommending it, practitioners risk good will, encouraging patients to pay thousands for a procedure they do not believe in themselves. A practice cannot be expected to push SculpSure to clients when the company that built the machine routinely fails to advise how to achieve results, how many treatments to perform, and how much pain patients should expect.

6. Performing the treatment also threatens to drain resources while taxing doctors and staff members. As the unsuccessful treatments add up, offices must futilely work with Cynosure to find a solution, deal with complaints from unsatisfied patients, and perform retreatments or alternative procedures.

7. Finally, continuing to own the machine jeopardizes these practices' financial health. The device's failures render it incapable of recouping its significant cost—a number that continues to grow with each refund or free retreatment necessarily offered to keep customers happy.

8. In short, Cynosure has marketed to physicians, aesthetic surgery facilities, and med spas a costly device that has proved unusable in those very practices.

9. SculpSure is thus effectively useless for the purpose for which it was intended. The device cannot be used in the way that Cynosure marketed it. Nor can it be used in an otherwise commercially viable manner.

10. Plaintiffs and the Class have been in fact deceived by Cynosure's representations, did not receive the benefit of the bargain, and suffered actual damages.

II. PARTIES

11. Plastic Surgery Associates, S.C. is a Wisconsin service corporation operating at N4W22370 Bluemound Rd, Waukesha, WI 53186. Plastic Surgery Associates provides cosmetic treatments, plastic surgery, and skin care to its patients, and bought a SculpSure in December 2015. Its purchase agreement with Cynosure refers to terms and conditions that provide, "[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Plastic Surgery Associates] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston." Plastic Surgery Associates was injured in its property and business by the actions of Defendant as described herein.

12. Infinity Spa Orlando, LLC operates at 25 West Kaley Street in Orlando, Florida. Infinity Spa Orlando specializes in facial and body contouring procedures. In June 2016, it acquired a SculpSure from Defendant pursuant to a purchase agreement subject to terms and conditions that provide, "[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Infinity Spa Orlando] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts." Infinity Spa Orlando was injured in its property and business by the actions of Defendant as described herein.

13. Green Chrysalis Enterprise, LLC is a Texas limited liability company doing business as The Face Place at 104 Grapevine Hwy, Suite 200, Hurst, TX 76054. The Face Place

offers various facial, cosmetic, and aesthetic medical treatments to its patients. It purchased SculpSure from Defendant in February 2016. The purchase agreement with Cynosure refers to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [The Face Place] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” The Face Place was injured in its property and business by the actions of Defendant as described herein.

14. Renew Skin & Laser Centers, LLC is a Virginia limited liability company doing business as Dermacare of Hampton Roads (“Dermacare”) at 747 Volvo Parkway in Chesapeake, Virginia. Dermacare operates as a med spa offering various cosmetic and aesthetic medical treatments to its patients. Dermacare purchased SculpSure from Defendant on December 15, 2015. That purchase agreement refers to terms and conditions that provide “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Dermacare] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” Dermacare was injured in its property and business by the actions of Defendant as described herein.

15. Arizona Advanced Aesthetics, PLLC is an Arizona professional limited liability company doing business as Enhanced Image Med Spa at 7942 W. Bell Rd., Glendale, AZ 85308. Enhanced Image Med Spa specializes in facial and body contouring procedures. In early 2016, Enhanced Image Med Spa acquired a SculpSure from Defendant pursuant to a purchase agreement subject to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Enhanced Image Med Spa] agrees to submit all disputes arising out of, or relating to, this Agreement to a

court in Boston, Massachusetts.” Enhanced Image Med Spa was injured in its property and business by the actions of Defendant as described herein.

16. Advanced Health Weight Loss, S.C. is a service corporation operating as Options Medical Weight Loss at 1147 S Wabash Ave. in Chicago, Illinois. It purchased a SculpSure in 2016. Its purchase agreement with Cynosure refers to terms and conditions that provide, “[the] Agreement shall be governed by and construed under the substantive laws of the Commonwealth of Massachusetts. [Options Medical Weight Loss] agrees to submit all disputes arising out of, or relating to, this Agreement to a court in Boston, Massachusetts.” Options Medical Weight Loss was injured in its property and business by the actions of Defendant as described herein.

17. Defendant Cynosure is a corporation incorporated and existing under the laws of Delaware with its principal place of business located at 5 W Carlisle Road, Westford, Massachusetts, 01886. Defendant Cynosure has developed and marketed several medical devices and lasers, including SculpSure, which it has sold to medical practitioners internationally.

III. JURISDICTION AND VENUE

18. This Court has jurisdiction and venue is proper because the action arises from acts and occurrences within the Commonwealth of Massachusetts, the Defendant Cynosure is headquartered in Westford, Massachusetts, and the parties agreed, via a choice-of-law provision and forum selection clause in their purchase agreements, to submit all disputes to a court in Boston, Massachusetts subject to Massachusetts law.

IV. FACTUAL BACKGROUND

A. The noninvasive body-contouring market is a lucrative place for medical device manufacturers to compete

19. Noninvasive body-contouring procedures constitute a large and rapidly growing sector of the cosmetic surgery market in the United States, with the number of treatments performed having increased by approximately 6% in 2016 compared to the previous year.¹

20. These procedures aim to eliminate stubborn fat from certain areas of the body. Body-contouring, however, differs from liposuction. Liposuction uses suction techniques to surgically extract fat deposits from specific areas of the body. Because liposuction requires anesthesia, it is typically an outpatient procedure at a surgery center, or if large amounts of fat are being removed, the procedure will be done in a hospital and may require an overnight stay. Patients typically return to work after several days and to normal activities within two weeks.²

21. Body-contouring, by contrast, uses noninvasive medical devices (*e.g.*, lasers) to eliminate or shrink fat cells without an incision or anesthesia. Practitioners most commonly (and most effectively) employ it to diminish small pockets of stubborn fat and reduce the circumference of a patient's midsection and flanks. These procedures are commonly performed in a physician's office or med spa without anesthesia and are appealing because they do not require any recovery time.³

¹ The American Society for Aesthetic Plastic Surgery, "2016 Cosmetic Surgery National Data Bank Statistics," at 12, *available at* <http://www.surgery.org/sites/default/files/ASAPS-Stats2016.pdf>.

² *Liposuction*, MAYO CLINIC (Nov. 29, 2016), <http://www.mayoclinic.org/tests-procedures/liposuction/home/ovc-20197272>; *How to Choose Between Liposuction and Noninvasive Fat Reduction Procedures*, AM. BD. OF COSMETIC SURGERY BLOG (Aug. 19, 2015), <http://www.americanboardcosmeticsurgery.org/liposuction/how-to-choose-between-liposuction-and-noninvasive-fat-reduction-procedures/>; *Liposuction*, MEDINCENET, <http://www.medicinenet.com/liposuction/page3.htm> (last visited September 21, 2017).

³ AM. BD. OF COSMETIC SURGERY BLOG, *supra* note 2; Deborah Kotz, *CoolSculpting and Zerona: Body Sculpting Without Surgery*, US NEWS & WORLD REPORT (Sept. 17, 2010, 1:26 p.m.), <http://health.usnews.com/health-news/blogs/on-women/2010/09/17/coolsculpting-and-zerona-body-sculpting-without-surgery>.

22. Body-contouring devices began appearing on the market approximately 10 years ago, and several companies have developed different technologies to achieve the desired results.⁴

23. For example, Zerona uses a low-level laser to target superficial fat cells. The laser does not destroy or kill the fat cells, but disrupts their membranes causing them to release their contents. The end result is that the affected fat cells shrink, causing a reduction in the belly, waist, or body size of the patient. Patients feel no pain. But because the treatment only targets superficial fat cells, it typically takes about six to twelve 40-minute treatments to achieve results.⁵

24. Another technology, CoolSculpting, uses a process called cryolipolysis to kill fat cells. Because fat cells freeze at higher temperatures than the surrounding tissue, the CoolSculpting device can deliver cold temperatures through the skin to freeze fat cells without damaging the skin. Targeted fat cells eventually die before the body removes them through its natural processes, yielding a reduction in size in the treated area. However, because the machine works by pulling a patient's skin into the device to apply very cold temperatures, patients frequently experience discomfort for the first five to 10 minutes of the procedure. The entire procedure takes about an hour, but unlike the Zerona procedure, CoolSculpting can often take only one visit to achieve results.⁶

⁴ AM. BD. OF COSMETIC SURGERY BLOG, *supra* note 2.

⁵ *How Does the Zerona Laser Work?*, MYZERONA.COM, <http://www.myzerona.com/what-is-zerona.html> (last visited May 8, 2017); R. Stephen Mulholland, Malcolm D. Paul, & Charbel Chalfoun, *Noninvasive Body Contouring with Radiofrequency, Ultrasound, Cryolipolysis, and Low-Level Laser Therapy*, 38 CLINIC IN PLASTIC SURGERY 503, 514-17 (2011), *available at* http://www.invasix.com/upload/articles/peerrev_clinps_titefxmension.pdf; Kotz, *supra* note 3.

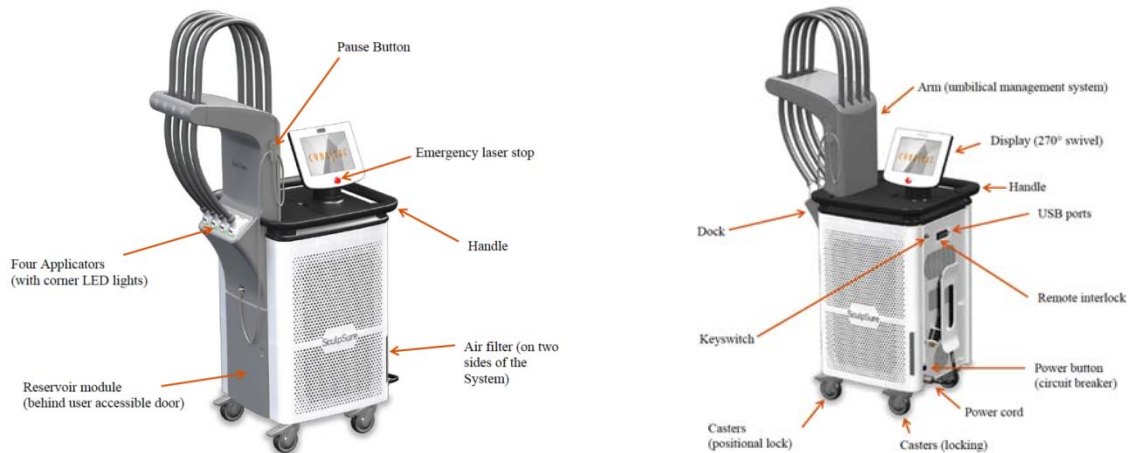
⁶ *How It Works*, COOLSCULPTING, <http://www.coolsculpting.com/what-is-coolsculpting/how-it-works/> (last visited May 9, 2017); *What To Expect*, COOLSCULPTING, <http://www.coolsculpting.com/what-is-coolsculpting/what-to-expect/> (last visited May 9, 2017); *FAQs*, COOLSCULPTING, <http://www.coolsculpting.com/what-is-coolsculpting/faqs/> (last visited May 9, 2017); Kotz, *supra* note 3;

B. Cynosure develops SculpSure to compete against other body-contouring machines

25. Cynosure, located in Westford, Massachusetts, is a corporation that specializes in the marketing and sale of medical devices utilizing laser technology for cosmetic and aesthetic use. Specifically in the area of noninvasive body-contouring, Cynosure sells a device it calls “SculpSure.”⁷

26. Cynosure developed and manufactured SculpSure from its Westford offices to compete in the noninvasive body-contouring market against Zerona, CoolSculpting, and similar devices. The machine uses a laser to heat adipose tissue (loose connective tissue in which fat cells accumulate⁸) to a temperature between 42°C and 47°C. Cynosure claimed this would cause the targeted fat cells to eventually die before being removed by the body’s lymphatic system.⁹

27. The machine has four long, flexible arms that are part of what Cynosure calls the “umbilical management system.” At the end of each arm is a rectangular applicator.¹⁰ Sample pictures follow:



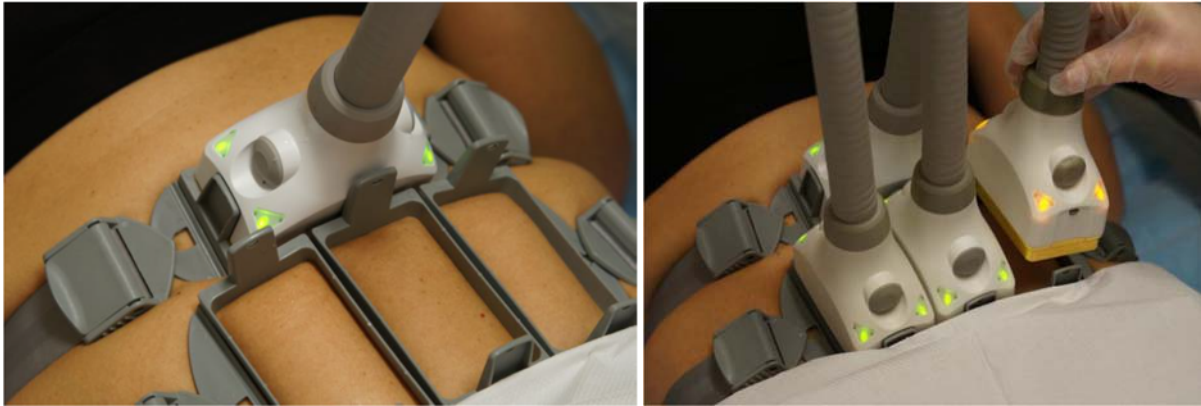
⁷ *About Cynosure*, CYNOSURE, <http://www.cynosure.com/about-cynosure/> (last visited May 9, 2010); *SculpSure*, CYNOSURE, <http://www.cynosure.com/product/sculpsure/> (last visited May 9, 2010).

⁸ *Adipose Tissue*, DICTIONARY.COM, <http://www.dictionary.com/browse/adipose-tissue>.

⁹ *SculpSure*, CYNOSURE, <http://www.cynosure.com/product/sculpsure/> (last visited May 9, 2010).

¹⁰ SculpSure Operator’s Manual (Rev. 4, Apr. 2016), at 12.

28. During the procedure, the operator arranges several plastic frames onto the patient's body in the treatment area, applies a lotion to certain areas of the patient's skin within those frames, and then attaches the rectangular applicators to the frames.¹¹



29. Each applicator used during the procedure consumes one “PAC.” PAC’s are credits that Cynosure loads onto a PAC Key. Without a sufficiently loaded PAC Key inserted into the USB port on the SculpSure, the machine will not function. Med spas and physicians must therefore purchase PAC Keys from Cynosure in advance before treating patients. As of April 2016, a PAC Key came loaded with 100 PAC’s and cost \$5,000.¹²

30. Once the applicators are in place, the operator initiates treatment. Treatment has two phases: “build mode” and “sustain mode.” Build mode occurs for the first four minutes of the procedure, during which the machine attempts to “heat[] the fat to the target temperature.” Sustain mode lasts the remaining 21 minutes and aims to “maintain[] the target temperature in the fat layer.”¹³

¹¹ SculpSure Clinical Reference Guide (Rev. 2), at 24-28.


¹² SculpSure Operator’s Manual (Rev. 4, Apr. 2016), at 36; CYNO - Q1 2016 Cynosure Inc Earnings Call, at 3 (Apr. 26, 2016).

¹³ SculpSure Clinical Reference Guide (Rev. 2), at 29.

31. The machine can deliver energy in a range of 0.90 to 1.40 Watts per square centimeter (W/cm^2), in increments of $0.05 \text{ W}/\text{cm}^2$. The build mode power density setting defaults to $1.10 \text{ W}/\text{cm}^2$.



32. Despite the default setting being set to $1.10 \text{ W}/\text{cm}^2$, SculpSure directs that the operator start at a low level and increase the power, adjusting the heat based on patient feedback. Initially, Cynosure released the following Zone Adjustment Chart to guide the treatment:¹⁴

Fat Destruction Zone	Zone Score	ZONE
	1	Pleasant cool/cold feeling. Increase setting.
	2	Gentle warming and cooling. Increase setting.
	3	Tingly, short intervals of warmth and cooling. No change in setting.
	4	Longer peaks of moderate deep warmth and cooling. No change in setting.
		Beyond Fat Destruction Zone. Select Advance-to-Cool button.

¹⁴ SculpSure Clinical Reference Guide (Rev. 2), at 32.

33. When the patient reports “moderate deep warmth and cooling” periods, the operator should maintain that level.¹⁵

34. According to Cynosure, at this point, the operator can leave the patient in the room with a “transmitter button to page [the staff]” in the event he or she patient experiences heat or discomfort beyond “moderate deep warmth and cooling.” The operator can then return to provide an “Advance-to-Cool” shot for temporary relief to the patient.¹⁶

35. At no time during the marketing of SculpSure did Cynosure report that patients would feel pain, have to endure heat to the point of an intense burning sensation, or require any painkiller or anesthesia.

C. Cynosure aggressively markets SculpSure to physicians and practitioners as a superior device requiring only one 25-minute, pain-free treatment to achieve results

36. The FDA cleared Cynosure to market its SculpSure device in mid-2015. Cynosure in turn planned to officially launch the product later that year.¹⁷

37. By autumn 2015, Cynosure was engaged in a motivated campaign to sell SculpSure to various cosmetic surgery providers, med spas, and practitioners across the country. From its Massachusetts headquarters, the company developed a consistent, uniform message to distinguish SculpSure from its competitors (namely CoolSculpting). Cynosure created videos (both for the practitioners to which it marketed and for use with the practices’ prospective clients), brochures, webpages, presentations, and other promotional materials reflecting that

¹⁵ *Id.*

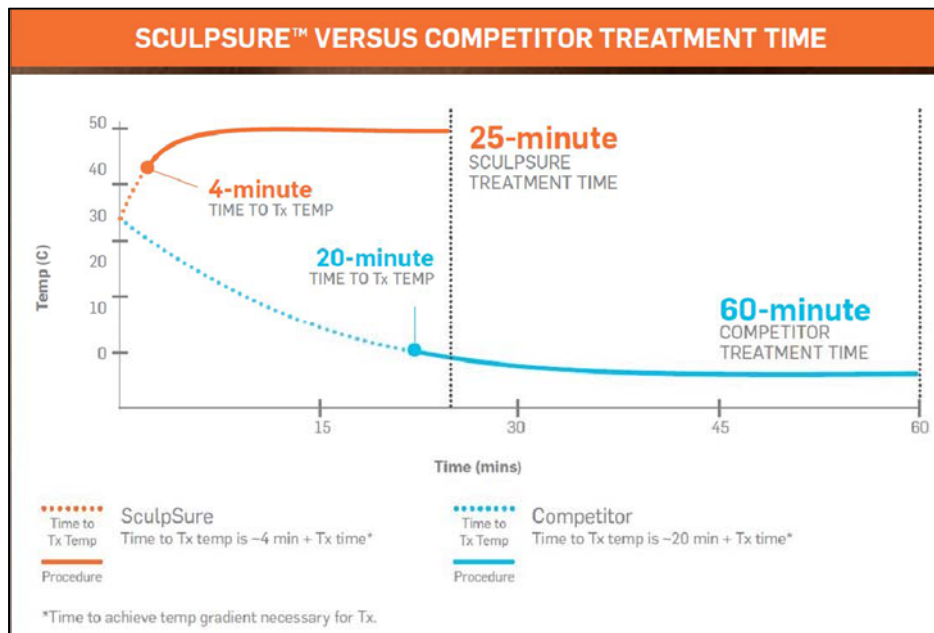
¹⁶ *Id.* at 31-32.

¹⁷ *FDA Clears Expanded Use for Cynosure Lipolysis Device*, MEDICAL PRODUCT OUTSOURCING (Jul. 7, 2015), http://www.mpo-mag.com/contents/view_breaking-news/2015-07-07/fda-clears-expanded-use-for-cynosure-lipolysis-device/.

consistent message.¹⁸ Cynosure distributed these materials to potential purchasers through its website, marketing department, and sales representatives.

38. Specifically, Cynosure emphasized three aspects of the device critical to purchasers.

39. First, Cynosure uniformly represented to potential buyers that patients would achieve “[d]efined success,” “[m]aximal performance,” or “optimal results” in one, 25-minute treatment. According to Cynosure’s website and marketing brochures, just one treatment would eliminate up to 24% body fat in the treated area.¹⁹ Before and after photos showed marked results from just “a single treatment in one anatomical area.” And by purportedly achieving these end results in only 25 minutes, Cynosure had a straightforward way to distinguish its product from CoolSculpting:²⁰



¹⁸ See Cynosure Investor Event (Presentation) (Sep. 15, 2015).

¹⁹ SculpSure, CYNOSURE.COM, <https://www.cynosure.com/product/sculpsure/> (last visited Aug. 17, 2017); SculpSure Product Presentation (Nov. 2015), at 8.

²⁰ SculpSure Product Presentation (Nov. 2015), at 7, 12-44.

40. This efficiency was particularly attractive to buyers. If the procedure truly took 25 minutes, those who owned a SculpSure could perform more treatments in a day without having to tax their staff, hire more employees, or perform follow-up with the patient. Furthermore, the minimal time commitment provided practices with a key marketing tool to convince patients to opt for the procedure, especially when compared to SculpSure's existing competitors.

41. Second, Cynosure stressed that the procedure would be a comfortable and pain-free experience for patients, despite the fact that SculpSure utilized very high temperatures to eliminate the fat cells.

42. According to Cynosure, SculpSure's "Contact Cooling" system would "assist in maintaining safe and comfortable skin surface temperatures." At the proper setting, Cynosure claimed that SculpSure would cause no more than "long[] peaks of moderate deep warmth and cooling."²¹ Cynosure's marketing materials assured that "[m]ost patients feel a tingling sensation intermittently which is well tolerated"²² and "[c]omfortable."²³ To demonstrate the tolerability of the procedure, Cynosure marketing videos showed women casually using cell phones, tablets, or e-readers during the procedure without any visible signs of discomfort and without any staff present in the room to monitor them.²⁴ Consistent with these representations, Cynosure also held live demonstrations at various promotional events where a model would sit and supposedly receive the treatment while talking to audience members to illustrate how painless the procedure was.

²¹ SculpSure Clinical Reference Guide (Rev. 2), at 9, 32.

²² SculpSure Marketing Brochure (2015), at 2.

²³ SculpSure Product Presentation (Nov. 2015), at 8.

²⁴ See, e.g., DocWeb, *SculpSure – Head to Head Treatment*, YOUTUBE (Jan. 16, 2016) <https://www.youtube.com/watch?v=Def18hMKFzI> (last visited Sep. 5, 2017).

43. To compare, CoolSculpting's suction mechanism and intense cold meant patients would have to endure at least a few minutes of discomfort during the procedure. So SculpSure offered the promise of attracting those patients who may be more hesitant to body contouring.

44. Third, Cynosure promoted the device as "hands-free,"²⁵ including a pager system with the device that would allow staff to "leav[e] the treatment room" but still communicate with patients. In its manual, Cynosure noted that a patient could use the transmitter to request "a magazine or water" during the treatment even though the staff member may not be in the room.²⁶ And in online promotional videos, Cynosure showed patients being left alone in the treatment room after only a few minutes:²⁷



²⁵ Cynosure Investor Event (Presentation) (Sep. 15, 2015).

²⁶ SculpSure Operator's Manual (Rev. 4, Apr. 2016), at 35.

²⁷ DocWeb, *SculpSure – Head to Head Treatment*, YOUTUBE (Jan. 16, 2016), <https://www.youtube.com/watch?v=Def18hMKFzI> (last visited Sep. 5, 2017).

45. If staff could leave the room, they could utilize their time more efficiently, assisting other patients, taking care of paperwork, or even performing a separate procedure. Potential purchasers naturally found this potential aspect of the device appealing.

46. All told, Cynosure's efforts to sell the machine promoting these supposed qualities were successful.²⁸ Cynosure has sold hundreds of SculpSures since 2015, with approximately 350 in the vicinities of five cities (Boston, Los Angeles, Miami, Chicago, and New York City) alone.²⁹

47. Hologic, Inc., who acquired Defendant for approximately \$1.44 billion in early 2017, consistently singled out SculpSure when discussing reasons for the massive acquisition of the company.³⁰

D. SculpSure does not work as represented, rendering the product effectively useless for practitioners and physicians

48. Nevertheless, Cynosure's representations about SculpSure proved to be false. In short, Cynosure misrepresented SculpSure's capability as a simple, one-and-done treatment without pain.

49. From the onset, patients failed to achieve results from SculpSure despite being treated as directed using Cynosure's Zone Adjustment Chart. Recognizing the problem, Cynosure subsequently revised its treatment protocol for SculpSure. In April 2016, Cynosure

²⁸ See CYNO - Q1 2016 Cynosure Inc Earnings Call, at 3 (Apr. 26, 2016) ("By virtually every measure SculpSure continues to exceed our expectation."); CYNO - Q2 2016 Cynosure Inc Earnings Call, at 3 (Jul. 26, 2016) ("Revenue for the quarter increased to a record \$110.3 million, 32% higher than the year-over-year period. The primary contributors to the top-line results were SculpSure, our exciting new hyperthermic laser treatment for noninvasive fat reduction . . ."); CYNO - Q3 2016 Cynosure Inc Earnings Call, at 3 (Oct. 25, 2016) ("I will now update you on SculpSure, which has generated meaningful revenue for the past four full quarters and continues to outperform our expectations."); CYNO - Q4 2016 Cynosure Inc Earnings Call, at 3 (Feb. 07, 2017) ("SculpSure, one full year into its launch, remains ahead of our expectations. Q4 set the high watermark for SculpSure placements in a single quarter.").

²⁹ See *Patients*, CYNOSURE, <http://patients.cynosure.com/> (searching for SculpSure machines located within 100 miles of the following zip codes: 02201, 90001, 33018, 60611, and 10018).

³⁰ HOLX - Hologic Inc to Acquire Cynosure Inc Conference Call, at 4, 6-7, 9 (2017)

introduced a “Treat to Complete” treatment plan, advising doctors to manage a patient’s “expectations that multiple treatments may be part of the treatment plan.”³¹ Yet the “Treat to Complete” protocol directly contradicted Cynosure’s marketing of SculpSure as a one-time, 25-minute treatment—with the latter message still advertised today on Cynosure’s website.³²

50. Furthermore, Cynosure directed physicians and practitioners to raise the power levels on the machine to compensate for poor results, contradicting prior claims that any setting between 0.9 and 1.4 W/cm² would suffice. Cynosure even suggested that once patients appear to have reached the threshold level they can tolerate, the operator should then “bump” the setting higher without the patient’s knowledge.

51. But even at lower power levels, many experienced excruciating pain. Practitioners reported that patients would jump off the treatment table, howl in agony, or even demand the operator stop the machine because they could not tolerate the procedure. Such circumstances paint a far different picture than the so-called “tingling sensation[s]” that Cynosure claims are “well-tolerated.”³³

52. The patient experience also makes it impossible for the operator to leave the treatment room and renders the pager system on the device useless. In practice, the procedure requires practitioners to stay in the room for the entire 25 minutes, and thus Cynosure’s promise of a “hand-free” treatment is untrue. Operators constantly need to adjust the device’s levels, provide “Advance to Cool” shots, or coach patients through the pain.

³¹ SculpSure Clinical Reference Guide (Rev. 4, Apr. 2016), at 15.

³² SculpSure, CYNOSURE.COM, <https://www.cynosure.com/product/sculpsure/> (last visited Sep. 5, 2017) (claiming that a “single treatment” provided “[d]efined success” with an “[a]verage reduction in fat volume” of “[u]p to 24%.”).

³³ SculpSure Marketing Brochure (2015), at 2.

53. Nor can practices simply administer anesthesia to make the procedure more bearable. The treatment requires feedback from patients to determine the appropriate energy level. If patients lack the ability to feel any pain or excessive heat in the treated area, then they cannot provide the necessary response to the doctor to lower the power level on the machine. Moreover, administering anesthesia would render the procedure inappropriate for med spas or other medical offices—the very practices for whom SculpSure was designed and to which it was marketed. And anesthesia, or even a strong oral analgesic, would require time before the procedure to administer it, downtime after the treatment to allow the patient to recover, and a doctor to monitor the patient to make sure he or she was fit to leave, any of which would render the promise of a 25-minute procedure false.

54. Given patients' painful experiences with the treatment, Cynosure had to update its Zone Score Adjustment Chart on multiple occasions. Initially Cynosure claimed that a power level correlating with "[t]ingly, short intervals of warmth and cooling" in the patient would result in "fat destruction." Yet by April 2016, it removed that claim. And but a few months later, Cynosure changed the chart again. This time it maintained that results would require "[p]rickling, pinching, pressure, [and] longer peaks of moderate deep heat and cooling"³⁴—an artful, yet still erroneous description of the distress many patients experienced. Not to mention, the description completely contradicts the one still advertised by Cynosure on its website: a "comfortable," "gentle, warming sensation" that "fl[ies] right by."³⁵


³⁴ Compare SculpSure Clinical Reference Guide (Rev. 2), with SculpSure Clinical Reference Guide (Rev. 4, Apr. 2016), and SculpSure Clinical Reference Guide (Rev. 7, Nov. 2016).

³⁵ SculpSure, CYNOSURE.COM, <https://www.cynosure.com/product/sculpsure/> (last visited Aug. 17, 2017) (claiming that a "single treatment" provided "[d]efined success" with an "[a]verage reduction in fat volume" of "[u]p to 24%.")


Rev. 2 (2015)

Fat Destruction Zone	Zone Score	ZONE
	1	Pleasant cool/cold feeling. Increase setting.
	2	Gentle warming and cooling. Increase setting.
	3	Tingly, short intervals of warmth and cooling. No change in setting.
	4	Longer peaks of moderate deep warmth and cooling. No change in setting.
		Beyond Fat Destruction Zone. Select Advance-to-Cool button.

Rev. 4 (April 2016)

Zone Score	ZONE
1	Pleasant cool/cold feeling. Increase setting.
2	Gentle warming and cooling. Increase setting.
3	Tingly, short intervals of warmth and cooling. Increase setting.
4	Longer peaks of moderate deep warmth and cooling. No change in setting.
	Beyond Fat Destruction Zone. Select Advance-to-Cool button.

Rev. 7 (August 2016)

Zone Score	ZONE
1	Pleasant cool/cold feeling. Increase setting.
2	Gentle warming and cooling. Increase setting.
3	Tingly, short intervals of warmth and cooling. Increase setting.
4	Prickling, pinching, pressure, longer peaks of moderate deep heat and cooling. No change in setting.
	Beyond Fat Destruction Zone. Select Advance-to-Cool button.

55. Ultimately, the situation has left practices in an impossible position. They have spent hundreds of thousands of dollars on a machine that does not work as Cynosure represented. At the same time, they lack the ability to recoup that cost; practices cannot continue to recommend a cosmetic procedure to their patients knowing that it is likely to involve several painful treatments, but unlikely to be effective.

E. Plaintiffs' experiences with SculpSure demonstrate how Cynosure uniformly misrepresented SculpSure's attributes and how the device remains unfit for its intended purpose

1. Plastic Surgery Associates cannot achieve results with SculpSure, leaving it with a useless device

56. Plastic Surgery Associates provides cosmetic treatments, plastic surgery, and skin care to patients from its facilities in Waukesha, Wisconsin. The practice is operated by Dr. Christopher Hussussian, and Dr. Thomas Korkos.

57. In mid-October 2015, Dr. Hussussian attended an American Society of Plastic Surgeons (ASPS) meeting in Boston, Massachusetts, where he first learned of SculpSure. Cynosure representatives presented the meeting goers with videos and marketing materials reflecting its uniform misrepresentations and describing SculpSure as cutting edge versus its competitors. The presentation claimed that SculpSure offered a significantly better patient experience compared to Coolsculpting while achieving the same end result. Specifically, Cynosure promised a reduction in fat of approximately 24% in less time than Coolsculpting, but with much less discomfort. In fact, the Cynosure booth contained a model who demonstrated SculpSure's advertised comfort level by talking to eventgoers while supposedly receiving an actual treatment.

58. Dr. Hussussian expressed interest in SculpSure at the event. So around November 2015 Cynosure sent a sales representative to visit the offices of Plastic Surgery Associates. The representative stressed several points, each consistent with the videos, presentations, and marketing materials produced by Cynosure to that point. She noted that SculpSure only required a one-time, 25-minute treatment, and was practically painless for patients such that it would not require any anesthesia or analgesic. Further, the device was so easy to operate, that the operator

could leave the room after only a few minutes and need not be present to adjust treatment levels throughout.

59. Given Cynosure's representations in their presentations, marketing materials, and meetings, Drs. Hussussian and Korkos opted to make the purchase.

60. In January 2016, Plastic Surgery Associates took delivery of the machine. Shortly thereafter, Krista Stoll from Cynosure came to its facilities to train the staff. During training, Ms. Stoll again reiterated what had been told to Plastic Surgery Associates to that point, both in marketing presentations and by the sales representative. Stoll stressed that one treatment should suffice to obtain results. She advised to adjust the levels on the machine based on patient comfort; any level within the range of 0.9 and 1.4 W/cm² could achieve optimal results. Plastic Surgery Associates then began treating patients according to the clinical reference guide, operator's manual, and in-person training.

61. By April 2016, Plastic Surgery Associates' patients had not seen any results. So Plastic Surgery Associates reached out to Cynosure who sent Ms. Stoll on May 24, 2016 to conduct a second training. At this second training, Cynosure introduced new straps and advised the staff of the "Treat to Complete" protocol. Ms. Stoll explained that a patient would now need more PACs applied to the treatment area and at least two treatments, which contradicted the original promise of a one-time procedure. Ms. Stoll also suggested that to achieve better results, the operator should "push" the settings higher.

62. Over the next several months, results with the machine did not improve. So on September 9, 2016, Plastic Surgery Associates held another meeting with Cynosure. At the meeting, Cynosure Practice Support Partners Maria Zuccherro and Kasey Lawrence emphasized operators would need to increase the levels and provide patients with multiple treatments. Ms.

Zuccherro offered complimentary PAC Keys to treat initial patients a second time. Following the meeting, Plastic Surgery Associates began contacting and retreating approximately 30 patients.

63. Two months later, Cynosure held a third training session at Plastic Surgery Associates, per the request of Tina Bock, a Cynosure Advanced Clinical Partner. Ms. Bock reiterated that the operator would need to “push” the settings higher during treatment to at least 1.1 or 1.2 W/cm² to get results. To accomplish this, she suggested that once the operator finds the appropriate level that patients can tolerate, the operator should then increase the settings without their knowledge. If the patient notices and cannot tolerate the higher level, the operator can then taper it back down.

64. But following Cynosure’s direction proved no more successful, and just caused further issues. By “pushing” the levels, patients often screamed in pain. Some screams echoed throughout the facilities, disturbing other patients and staff while creating an unsettling atmosphere throughout the office. Many patients simply could not tolerate the pain and demanded it be stopped. And someone had to be in the treatment room at all times to monitor the patient and treatment levels, proving the promise of a “hands-free” treatment from Cynosure’s marketing false.

65. In June 2017, Plastic Surgery Associates requested a refund for the device. Cynosure’s Regional Sales Director for the Midwest took the position it could not offer a refund because the practice also owned a CoolSculpting device, and has since ceased responding to Plastic Surgery Associates regarding SculpSure.

66. Since the June 2017 meeting, Plastic Surgery Associates has pulled its marketing for the device. It has also stopped recommending the procedure, directing patients toward CoolSculpting instead, with which it has obtained significantly better results. The staff has

completely lost faith both in SculpSure's effectiveness, as well as Cynosure's willingness to do anything about the problems with the device.

2. Infinity Spa cannot in good faith recommend SculpSure to its clients after patients consistently report excessive pain but fail to achieve positive results even after several treatments

67. Infinity Spa Orlando is a boutique med spa located in Orlando, Florida, and managed by Lisa Christensen, M.D., Sharon Gallardy, A.R.N.P., and Diane Orlando, A.R.N.P.

68. In December 2015, Ms. Gallardy and Ms. Orlando attended a conference at the Loews Portofino Bay Hotel in Orlando, Florida held by Cynosure. There, doctors and representatives from Cynosure presented its new device, SculpSure. Using PowerPoint presentations and promotional videos, speakers described the science and technology and praised certain aspects of the treatment and experience. In particular, the presenters highlighted SculpSure's: (1) results—save a few exceptions, patients saw a 20-24% decrease in fat after just one treatment; (2) treatment experience—the treatment lasted just 25 minutes and the operator could leave the room; and (3) tolerability—patients reported little to no pain. Videos played for the audience showing patients smiling during the procedure and experiencing no discomfort while the operator left the room. And Cynosure even gave a live demonstration of the treatment, where a Cynosure employee supposedly received the treatment without showing any signs of distress.

69. Cynosure's presentations at the conference impressed Gallardy and Orlando, who then discussed purchasing the device with Christensen. In early 2016, the three contacted Cynosure.

70. Cynosure sent them emails, repeating the claims above, and included links to marketing materials, videos, and presentations that similarly promoted the results, treatment experience, and tolerability of the procedure. Consistent with those materials, Cynosure's sales

representative aggressively hyped the machine in writing, reiterating the same points. The representative stated that “in 25 min with no discomfort . . . Sculpsure will destroy 25% of a person’s fat.” He further noted the operator could leave during the procedure, telling Infinity Spa to “KEEP IN MIND THE PROCEDURE IS UNATTENDED SO ONCE YOU HOOK THEM UP AND START THE LASER YOU CAN DO OTHER THINGS.” The “bottom line,” according to the representative, was that SculpSure took only “25 minutes,” “melt[ed] 25% of a patient[’]s fat during 1 treatment,” and would be “painless.”

71. In June 2016, via a financing agreement with Ascentium Captial, Infinity Spa purchased a SculpSure for \$165,123.75 based on these representations.

72. Training occurred shortly thereafter with Lindsay Webber from Cynosure. As part of training, Webber treated Christensen, Gallardy, and Orlando. Ms. Orlando immediately realized the treatment’s capacity for serious pain, describing it as similar to experiencing labor contractions without any pain medication. Gallardy also found the experience uncomfortable, and not at all in tune with the descriptions provided by Cynosure up until that point. Not one of them achieved results at any point.

73. Infinity Spa treated a few patients over the summer and fall, none of whom fared better. The treatment caused pain and patients reported a lack of results. Infinity Spa in turn reported its dissatisfaction to Cynosure. So in November 2016, Cynosure contacted Infinity Spa to “check up” on the practice and arrange a second training, this time with Mary Bots. But the second training proved no more encouraging.

74. At the second training, Bots oversaw Dr. Christensen treat Gallardy, who found the procedure so painful she experienced presyncope (the state of lightheadedness, nausea, and

blurred vision that precedes fainting, but without losing consciousness). The pain even carried over into the following days, when the treated area became red, swollen, and inflamed.

75. About a month later, in December 2016, Infinity Spa asked to meet with Cynosure representatives before a conference being held in Orlando. While seemingly reluctant, Cynosure eventually acquiesced, and the parties met for approximately an hour before the conference to discuss Infinity Spa's lack of results. Cynosure proposed that Infinity Spa offer to retreat its patients twice more for a total of three treatments, claiming for the first time that multiple treatments may be needed to see results. Cynosure said that it would reimburse Infinity Spa for the money spent on PAC's for these retreatments. Infinity Spa agreed and retreated all of its prior patients for a second and third time. None achieved results.

76. SculpSure has left Infinity Spa in a predicament. The machine cost the business a significant amount of money. But given their own dreadful experiences with the procedure and their clients' universal dissatisfaction, the staff has found it impossible to recommend SculpSure in good faith. The business thus lacks the ability to recoup the expense, to say nothing of the time and good will lost trying in vain to make it work.

77. In March 2017, Infinity Spa asked Cynosure to take back the laser for a refund. Cynosure refused. Lacking any other viable option, Infinity Spa informed Ascentium Capital that it could repossess the device.

3. The Face Place attempts to make SculpSure work for over a year to the detriment of its practice

78. The Face Place operates in the Dallas-Fort Worth area of Texas, and provides various cosmetic procedures to its clients. The Face Place is run by its Practice Manager and owner, Donna Green.

79. In February 2016, Ms. Green had been contemplating the purchase of a CoolSculpting device for her practice so she placed a call to a CoolSculpting sales representative. While she waited to hear back, Lance Baird of Cynosure approached her. Baird wanted to promote SculpSure, which he declared would “put CoolSculpting out of business.” According to Baird, a single 25-minute procedure, achieved results “equal to” or “better” than CoolSculpting but “with less discomfort.” He described the procedure as very tolerable, with no medications or anesthetics needed. And he boasted that that Cynosure has “actually had tons of coolsculpt customers (some with multiple units) purchasing SculpSure for their practices because faster and less pain is what every patient wants, and more profitable is what every business owner wants.”

80. Baird followed up by providing Green with Cynosure’s marketing materials, all of which proved consistent with Baird’s sales pitch. One video claimed a single 25-minute treatment would destroy up to 24% of subcutaneous fat.³⁶ Another video portrayed a practitioner treating two patients in the time it took CoolSculpting to treat one while leaving the treatment room for both.³⁷ And an online article stated “most patients feeling nothing more than a deep warming sensation.”³⁸

81. On February 29, 2016, Baird came to The Face Place to meet with Ms. Green. Baird once again made claims consistent with the marketing materials regarding SculpSure being a painless, one-time treatment with results comparable or better to CoolSculpting. Green, relying

³⁶ Face RX Md, *How SculpSure™ Works* (Nov. 8, 2015), <https://www.youtube.com/watch?v=vhdwEFURh9Y> (last visited Aug. 15, 2017).

³⁷ Medical Spa Lasers, *SculpSure- The Ice Age is Over* (Oct. 21, 2015), <https://www.youtube.com/watch?v=6yn0gPSKSU> (last visited Sep. 6, 2017).

³⁸ Sheryl Kraft, *A New Way to Get Rid of Unwanted Fat*, MYSOCALLEDMIDLIFE, (Feb. 15, 2016), <http://sherylkraft.com/a-new-way-to-get-rid-of-unwanted-fat/>.

on these representations, agreed to buy the device and the next day began working with Heartland Business Credit to finance the \$167,250.00 purchase price.

82. Cynosure delivered the device in early March 2016, with training occurring shortly thereafter. Melissa Williams and Sonja McDonnell attended from Cynosure. During training, Williams and McDonnell repeated the same claims from Cynosure's marketing efforts. They told Ms. Green and her staff that the device was the "easiest laser" they would ever operate. The procedure was so simple and painless, they claimed, that the operator could leave the room after a few minutes to perform a Botox treatment on another client while SculpSure finished the job. But these claims would be immediately contradicted by the ensuing events.

83. As part of training, the two Cynosure representatives performed SculpSure on Ms. Green and her staff. But the level of pain she witnessed did not at all resemble what had been promised. One staff member described it as feeling like her "skin was going to come off." Green's own treatment was agonizing. And all six who received the treatment reported at the very least extreme discomfort.

84. Williams and McDonnell acted surprised by the staff's inability to tolerate the pain, and assured them that the procedure would be indeed quite tolerable for patients and the situation was simply a unique case.

85. Following training, The Face Place began taking patients. Yet these people fared no better. Patients repeatedly complained about the pain of the procedure, with several claiming they would never go through it again nor recommend it to others.

86. In June 2017, Dupree emailed to Green Cynosure's most recent recommended treatment protocols. Now Cynosure recommended *at a minimum* to treat two separate areas, at 25 minutes an area, in two separate sessions—or approximately two hours of treatment time. At

the other end of the spectrum, Cynosure recommended treating six separate areas (at 25 minutes each area) in three separate sessions—or over 7.5 hours of treatment time. In other words, Cynosure’s initial promise that patients could undergo a one-time, 25-minute treatment and achieve a 20-24% reduction in body fat had slowly evolved into a recommendation that patients undergo a series of multiple treatments spanning several hours and involving different sessions to achieve their “desired goals.” Cynosure’s new protocol revealed a lack of faith in the effectiveness of its own machine.

87. As Cynosure failed to deliver consistent information about the device or provide guidance as to how to remedy any of its issues, Green grew frustrated. The procedure strained her practice, both mentally and financially. It had not been the so-called “easiest laser” to operate, always requiring someone in the room with the patients to coach them through the pain. Customers routinely complained, both of the pain and lack of results. And, unlike with other treatments, they never provided referrals following their results. Refunds or courtesy treatments were common.

88. In short, SculpSure failed as a viable treatment in her practice and threatened her reputation.

89. By June 2017, The Face Place stopped actively selling the procedure. Come July, it decided to no longer sell the treatment and asked Cynosure for a refund; the request has gone unanswered.

4. Dermacare’s SculpSure goes unused after constant complaints regarding pain and poor results

90. Dermacare of Hampton Roads is a med spa in Chesapeake, Virginia, offering various cosmetic and aesthetic medical treatments to its patients.

91. In May 2015, Dermacare received an email from Cynosure introducing SculpSure. In that email, Cynosure touted that “SculpSure™ is a clinically proven and safe treatment designed to reduce fat non-invasively by disrupting subcutaneous fat cells with a hands free treatment in just 25 minutes.” The email contained a quote from CEO Michael Davin stating that SculpSure is “*highly effective in reducing adipose tissue and does so in significantly less time than other current treatments.*” Davin also claimed that “*the combination of these benefits enables us to offer practitioners the lowest total cost of ownership of any non-invasive lipolysis treatment on the market today, which in turn significantly enhances their return on investment.*”

92. In late-November 2015, Dermacare’s owner, Leon Garber, also heard about SculpSure from a friend. So Garber reached out in early December to a sales representative for Cynosure with whom he had previously discussed other products. During that phone call, the sales representative repeated the same promises from Cynosure’s marketing; namely that SculpSure: (a) was equally or more effective than its competitors in just one 25-minute treatment; (b) was “pain-free;” and (c) was so easy to use the operator could leave the room during the procedure.

93. Based on Cynosure’s these representations and Cynosure’s marketing, Garber decided in mid-December to acquire a SculpSure for Dermacare.

94. Cynosure delivered the device to Dermacare on January 12, 2016. In mid-February, a Cynosure representative visited Dermacare’s offices to provide on-site training for Dermacare staff. During that training, the Cynosure representative again represented SculpSure as a one-and-done treatment. The representative further explained that Dermacare’s staff member need only be present for the initial five minutes during “build mode.” After that, staff

members could attend to other matters, leaving the patient in the room with a buzzer to page them should the patient feel uncomfortable and need an “Advance-to-Cool” shot.

95. Following training, Dermacare staff practiced using the machine for approximately two weeks before beginning to treat patients using the recommended Zone Adjustment Chart in early March 2016. According to Cynosure, Dermacare would end up treating most patients at about 1.0 W/cm² using this method, and achieve results. But in practice, Dermacare’s patients saw no results being treated at this level.

96. Patients began complaining to Dermacare about their results with SculpSure immediately, beginning in late-April. By July 2016, Dermacare attempted to remedy the problem by offering dissatisfied patients retreatment with the device at no charge. Yet retreatment did not prove successful either.

97. Nor could Dermacare simply turn the power level up. Many patients reported intolerable pain, especially at higher levels. In some instances, the pain prompted patients to curse, scream, or jump off the treatment table.

98. By September 2016, Dermacare’s staff could no longer trust the device and Garber recognized that his practice would suffer should he continue to perform SculpSure on his clients. Instead of experiencing a so-called “combination . . . of benefits,” Garber had experienced a series of problems. And instead of experiencing the “low[] cost of ownership,” Garber had been providing free retreatments and refunds, while making massive monthly payments and paying for consumable PAC Keys. Around this time, Dermacare stopped using the machine almost entirely.

99. Despite its SculpSure now going unused, Dermacare must continue to pay \$3,712.68 monthly to lease the device. And since the device’s shortcomings leave Dermacare

with no ability to recoup that cost, SculpSure remains a constant drain on the finances of the company.

5. SculpSure proves unworkable for Enhanced Image Med Spa and threatens the financial health of the business

100. Enhanced Image Med Spa offers a variety of cosmetic, facial, and laser treatments from its offices in Glendale, Arizona. It is run by Jennessa Iannitelli, D.O.

101. In late-2015, Enhanced Image had been working with Sharon Knecht from Cynosure to trial Cynosure's Elite device for its practice. While working together, Knecht suggested Enhanced Image also consider purchasing SculpSure.

102. Knecht introduced Dr. Iannitelli to another Cynosure sales representative, Justin Thompson. Thompson quickly forwarded Dr. Iannitelli SculpSure promotional materials and videos advertising the results achieved in a single 25-minute treatment, the absence of pain, and the "hands-free" operation.

103. Consistent with the marketing materials, the representatives claimed that SculpSure would be pain-free and easily tolerable; the device would merely produce a warming sensation and would not require anesthetic or analgesics. Thompson and Knecht likewise stressed the impressive results SculpSure could achieve, asserting the device would eventually replace Dr. Iannitelli's liposuction practice. Thompson and Knecht repeated the claims from Cynosure's marketing brochures: just a single 25-minute treatment would achieve visible results in the form of a 20-24% fat reduction in the treated area. Lastly, they explained SculpSure's ease of use, noting that operators simply had to initiate the procedure for a few minutes before they could leave the room and do something else around the office.

104. Based on all of these representations about SculpSure, Dr. Iannitelli agreed to purchase a demo unit, financing the \$163,750 sales price with Ovation Finance.

105. Following delivery of the device, on February 23, 2016, Sheena Kapukui of Cynosure visited Enhanced Image to train Dr. Iannitelli and the staff. As part of that training, Kapukui performed treatments on three of those present, where the device initially demonstrated a potential for problems. One of the staff members had difficulty tolerating the procedure because of the excess heat and pain it caused her. And none of those treated showed any results, to say nothing of the 24% reduction promised.

106. The problems only continued. Many of the practice's initial patients reported being miserable from the excess heat and pain, and some accused the practice of lying about SculpSure's tolerability. One patient demanded that the treatment be stopped mid-procedure and stormed out of the office.

107. Nor did SculpSure produce results. Patients continuously failed to demonstrate any fat loss, even after multiple treatments. Indeed, some staff members had been treated up to four times, and still did not see results. Some upset patients referred to the practice as "snake oil salesmen."

108. In early December 2016, during a third training session with SculpSure, Dr. Iannitelli and her staff aired their frustrations to Wanda Cummings, a consultant for the company. Cummings responded that Cynosure should not have made the promises it did—namely, regarding SculpSure's efficacy, propensity for pain, and functionality—for none of them were true.

109. Ultimately, Enhanced Image had to cease performing the procedure on patients. It simply could not continue to recommend SculpSure in good faith to patients when Dr. Iannitelli and the staff did not believe the machine could produce the results the patient sought. To otherwise continue to treat patients risked harming the practice. Enhanced Image had already

lost plenty of clients and good will from the many painful and unsuccessful treatments to that point. It could not afford to lose more. SculpSure now goes unused, unable to recoup the massive costs—financial and otherwise—it has cast upon the practice.

6. Options Medical Weight Loss refunds nearly all of its patients treated with SculpSure due to poor results

110. Options Medical Weight Loss is a weight loss center in Chicago, Illinois. It is run by William Barton, Dr. Matt Walker, and Dr. Katrina Mattingly.

111. In 2016, Mr. Barton began researching body contouring devices for use in the Options Medical Weight Loss center. He initially expressed interest in a purchasing a CoolSculpting device and posted on Facebook seeking input. That Facebook post led him speaking to a woman who recommended that he also look at SculpSure. Barton contacted Cynosure to learn more.

112. On September 19, 2016, Barton met with Brad Hohenstein of Cynosure. Hohenstein wasted no time detailing all of the ways that SculpSure beats CoolSculpting, mirroring the promises made in Cynosure's marketing. He noted that SculpSure achieves up to 24% fat reduction in just one 25-minute treatment. Hohenstein also remarked on the lack pain during the procedure and the simplicity of operating the device, which allowed the operator to leave the room.

113. Cynosure sales representatives also emailed Barton providing links to marketing materials and videos, repeating these claims. For example, one marketing brochure stated that one 25 minute procedure would "permanently destroy up to 24% of treated fat." And videos showed the operator leave the room while the patient casually received the treatment without any pain.

114. Based on Cynosure's uniform representations, Barton, Walker, and Mattingly opted to purchase the device.

115. Following delivery, Tina Bock from Cynosure came to Options Medical Weight Loss Center in the Fall of 2016 to train the staff. As part of the training, Bock treated any staff members who would volunteer. Once one staff member suffered from searing pain, the rest of the staff refused to volunteer.

116. Bock also advised the staff of the "Treat to Complete" protocol, where some patients with a higher body mass index may require multiple procedures to get results. This was the first anyone from Options Medical had heard of "Treat to Complete" or the need for additional treatments; all of the marketing Options Medical had seen or heard to that point claimed the device was effective after one session.

117. Similarly, it soon became clear that the level of pain far exceeded that which Cynosure had advertised in its marketing. Some patients described it as "intense" or "excruciating." And given the discomfort of the patients, the staff, which had been scheduled to work on other things, could not leave the room.

118. The patients' pain did not pay off with results either. Patients complained. One even filed a complaint with the FDA, claiming the device does not work. By early 2017, Barton found himself having to refund (or offer free services) to almost every patient who had received SculpSure.

119. Barton has unsuccessfully attempted to work with Cynosure about the device's shortcomings and the unsatisfied customers.

120. Because Cynosure will not take back the machine and because he cannot keep recommending the procedure to his clients, Barton has looked to sell the machine. But to date

has been unable do that either because he cannot find anyone willing to purchase it, let alone for an amount close to what he paid for it. Instead, the device goes unused while Options Medical continues to make payments on the device.

V. CLASS ALLEGATIONS

121. Plaintiffs bring these claims pursuant to Massachusetts General Law 93A § 11 (“G.L. 93A”) and Rules 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure. They file this action on behalf of themselves and a Nationwide Class defined as follows:

All individuals and entities in the United States who purchased or leased a SculpSure Non-Invasive Body Contouring Platform.

The definition of the Class is unambiguous. Plaintiffs are members of the Class that they seek to represent.

122. Under Rule 23, an action may be maintained as a class action if: (1) “the class is so numerous that joinder of all members is impracticable;” (2) “there are questions of law or fact common to the class;” (3) “the claims or defenses of the representative parties are typical of the claims or defenses of the class;” and (4) “the representative parties will fairly and adequately protect the interests of the class.”³⁹ Plaintiffs’ action meets each of these requirements.

A. Plaintiffs bring their claims on behalf of numerous others

123. The exact number of Class members is unknown and not available to Plaintiffs. But since receiving FDA 501(k) clearance in the third quarter of 2015, Defendant has sold SculpSure nationwide to hundreds of Class members, making joinder of each individual member impracticable. Ultimately, Class members can be identified through Defendant’s records.

³⁹ Fed. R. Civ. P. 23(a)(1)-(4).

B. Plaintiffs and the Class are similarly situated and have suffered similar injuries

124. Common questions of law and fact predominate over the questions affecting only individual Class members. Some of the common legal and factual questions include:

- a. Did Cynosure promote the treatment as “painless,” “tolerable,” “comfortable,” or similarly, despite the fact that it caused great discomfort or serious pain to many patients?
- b. Did Cynosure misrepresent the effectiveness of the procedure to prospective purchasers?
- c. Did Cynosure market the treatment as “one-and-done,” “one-time,” or in a similar manner, despite questionable efficacy even after multiple treatments?
- d. Did Cynosure promise purchasers that their staff members could leave the room during the procedure, when in fact the SculpSure operator would need to remain in the room to monitor the patient throughout the procedure?
- e. Did Cynosure’s representations to the Class accurately reflect its own knowledge and research?

125. All of the claims asserted by Plaintiffs are common to and typical of the Class. Plaintiffs and the Class all complain of the same product, SculpSure, and the same wrongful conduct by Cynosure in marketing that product. The misrepresentations that Cynosure made to Plaintiffs and the Class have been uniform, namely that SculpSure: (a) involves only one, simple 25-minute treatment to achieve 24% fat loss; (b) is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) can be performed “hands free” without a physician and/or trained staff member present during the entire procedure.

126. Likewise, Plaintiffs and the Class have suffered similar damages. Plaintiffs and the Class did not receive the benefit of the bargain and lost money in the amounts spent purchasing or leasing SculpSure, buying consumable PAC Keys, and retreating patients.

127. The class action device is thus superior to other available means for the fair and efficient adjudication of the claims of Plaintiffs and the Class members. The relief sought per individual member of the Class is small compared to the burden and expense that would accompany the individual prosecution of every Class member. Furthermore, it would be difficult, if not impossible, for the Class members to seek redress on an individual basis. Even if the Class members themselves could afford such individual litigation, the court system could not.

128. Individual litigation of the legal and factual issues raised by the conduct of Defendant would increase delay and expense to all parties and to the court system. The Class action device presents far fewer management difficulties and provides the benefits of a single, uniform adjudication, economies of scale, and comprehensive supervision by a single court. Given the similar nature of the Class members' claims and the application of a singular state law (due to Defendant's choice of law provision selecting Massachusetts), the Court and the parties can easily manage a nationwide Class.

C. Plaintiffs and the Class will be adequately represented

129. Plaintiffs will fairly and adequately represent and protect the interests of the Class, and has retained counsel competent and experienced in complex litigation, including class actions. Plaintiffs have no interest antagonistic to those of the Class, and Defendant has no defenses unique to the Plaintiffs.

VI. CLAIMS ALLEGED

COUNT I VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT (G.L. CHAPTER 93A)

130. Plaintiffs hereby incorporate paragraphs 1 through 129 as if fully set forth herein.

131. This cause of action is brought by Plaintiffs pursuant to the Massachusetts Consumer Protection Act, G.L. Chapter 93A §§ 2, 11 *et. seq.*, on behalf of the Class. Section 2 of the Massachusetts Consumer Protection Act provides that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”

132. Plaintiffs, Class Members, and Defendant are “persons” under the Massachusetts Consumer Protection Act pursuant to G.L. Chapter 93A § 1(a).

133. SculpSure is tangible property involved in “trade” and “commerce” subject to the Massachusetts Consumer Protection Act pursuant to G.L. Chapter 93A § 1(b).

134. At all relevant times, Defendant violated and continues to violate the Massachusetts Consumer Protection Act in its transactions regarding SculpSure. Specifically, Defendant deceives buyers by misrepresenting certain qualities and attributes of the SculpSure procedure. Defendant uniformly misrepresented to potential buyers that:

(a) SculpSure requires only one 25-minute treatment to achieve 24% fat loss, when in fact it requires multiple treatments and still is likely to be ineffective;

(b) the treatment was virtually painless and easily tolerable without any pain medication or anesthesia, when in fact it is very painful and patients routinely could not tolerate the procedure; and

(c) SculpSure could be performed “hands free” without a physician or trained staff member present during the entire procedure, when in fact one was required at all times to monitor energy levels.

135. Defendant’s deception has caused substantial injury to Plaintiffs and the Class. Plaintiffs and the Class cannot recommend a procedure that involves several painful treatments and still does not yield any meaningful result in the patient. And so they have spent hundreds of thousands of dollars on a machine that is ultimately inappropriate for their practice and does not work in a commercially viable way. The machine effectively goes unused, not only denying Plaintiffs and the Class the ability to make a profit, but also the opportunity to recoup the sizeable costs already incurred. Plaintiffs and the Class have lost money and had their businesses placed under considerable financial strain.

136. Accordingly, as a direct and proximate result of Defendant’s deceptive acts and practices, Plaintiffs and the Class did not receive the benefit of the bargain, suffered actual damages, and are entitled to trebling, plus attorneys’ fees and costs.

COUNT II BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

137. Plaintiffs hereby incorporate paragraphs 1 through 129 as if fully set forth herein. Under Massachusetts law, “a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind.”⁴⁰ To be merchantable, goods must at least be “fit for the ordinary purposes for which such goods are used.”⁴¹

⁴⁰ Mass. Gen. Laws Ann. ch. 106, § 2-314(1).

⁴¹ Mass. Gen. Laws Ann. ch. 106, § 2-314(2)(b).

138. Defendant is a merchant under Massachusetts law who specializes in the marketing and sale of medical devices utilizing laser technology for cosmetic and aesthetic use. Defendant designed, manufactured, and marketed SculpSure, a noninvasive body-contouring device from its offices in Massachusetts.

139. Beginning in late 2015, Defendant marketed and sold the SculpSure device all over the country. In selling the device, Defendant specifically targeted cosmetic and aesthetic medical practices, including small medical offices and med spas. In selling to those customers, Defendant represented that SculpSure would be appropriate for their practices, namely because it: (a) involves only one, simple 25-minute treatment to achieve 24% fat loss; (b) is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) could be performed “hands free” without a physician and/or trained staff member present during the entire procedure.

140. At no time, however, has SculpSure actually been suitable for the ordinary purposes for which it is intended. Even when Plaintiffs and the Class use the machine as envisioned by Defendant’s marketing and as directed by Defendant, SculpSure cannot successfully be performed as a one-time treatment, frequently causes significant pain in the patient, and requires hands-on assistance from a physician or trained staff member to administer the treatment. It is thus not fit for use in medical spas, physician offices, or as otherwise marketed by Defendant.

141. As a consequence, Plaintiffs and the Class have spent hundreds of thousands of dollars on a machine that is not suitable for their practices. Plaintiff and the Class have lost money and had their businesses placed under considerable financial strain. Accordingly,

Plaintiffs and the Class did not receive the benefit of the bargain, suffered actual damages, and are entitled to trebling, plus attorneys' fees and costs.

**COUNT III
UNJUST ENRICHMENT**

142. Plaintiffs hereby incorporate paragraphs 1 through 129 as if fully set forth herein.

143. From late 2015 to the present, Plaintiffs and the Class have purchased hundreds of SculpSure machines from Defendants. In turn, Defendant has received millions of dollars in revenue from Plaintiffs and the Class via purchases of the machine, lease agreements, and the sale of PAC Keys.

144. Defendant has frequently touted the success of its sales of SculpSure, directly attributing the company's record revenues to sales of the machine.⁴² Likewise, Hologic, Inc., who acquired Defendant for approximately \$1.44 billion in early 2017, consistently singled out SculpSure when discussing reasons for the massive acquisition of the company.⁴³

145. Defendant's enormous financial gains, however, come at the expense of the financial distress placed upon Plaintiffs and the Class. Plaintiffs and the Class purchased SculpSure because Defendant marketed the device as not only suitable for their practice, but as premier technology. Defendant touted certain attributes, namely that SculpSure: (a) involves only one, simple 25-minute treatment to achieve 24% fat loss; (b) is virtually painless and easily tolerated by the patient without pain medication or anesthesia; and (c) could be performed "hands free" without a physician and/or trained staff member present during the entire procedure.

146. But in practice SculpSure has shown to possess none of these characteristics. The procedure cannot successfully achieve results as a one-time treatment. SculpSure causes

⁴² CYNO – Q2 2016 Cynosure Inc Earnings Call, at 3 (Jul. 26, 2016).

⁴³ HOLX – Hologic Inc to Acquire Cynosure Inc Conference Call, at 4, 6-7, 9 (2017)

significant pain in countless patients. And requires hands-on assistance from a physician or trained staff member to administer the treatment. Because Plaintiffs and the Class cannot recommend a procedure that involves several painful treatments and does not yield any meaningful results, the machines effectively go unused.

147. Accordingly, it would be inequitable and unjust for Defendant to retain its ill-gotten fortune. Plaintiffs and the Class did not receive the benefit of the bargain, suffered actual damages, and are entitled to trebling, plus attorneys' fees and costs.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Class, respectfully request that this Court issue an order:

- a) Certifying this case as a class action on behalf of the Class defined above, appointing Plaintiffs as class representatives, and appointing its counsel as class counsel;
- b) Finding that Cynosure breached the implied warranty of merchantability, violated the Massachusetts Consumer Protection Law, and was unjustly enriched;
- c) Awarding Plaintiffs and the Class all appropriate damages, including trebling;
- d) Awarding Plaintiffs and the Class restitution in the form of complete disgorgement of all revenue derived from sales or leasing of the SculpSure product;
- e) Awarding Plaintiffs and the Class their reasonable litigation expenses and attorneys' fees;
- f) Entering such other injunctive and/or declaratory relief as necessary to protect the interests of Plaintiffs and the Class; and
- g) Awarding such other and further relief as equity and justice may require.

VIII. JURY DEMAND

Plaintiffs demand a trial by jury for all issues so triable.

Dated: September 27, 2017

Respectfully Submitted,

HAGENS BERMAN SOBOL SHAPIRO LLP

By: /s/ Lauren Guth Barnes

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